



US006475185B1

(12) **United States Patent**  
**Rauker et al.**

(10) **Patent No.:** **US 6,475,185 B1**  
(45) **Date of Patent:** **Nov. 5, 2002**

(54) **OCCLUSION DEVICE**

(75) Inventors: **Robert M. Rauker**, Maple Grove, MN (US); **Peter J. Gafner**, Ham Lake, MN (US)

(73) Assignee: **SciMed Life Systems, Inc.**, Maple Grove, MN (US)

(\*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

5,536,252 A	7/1996	Imran et al. ....	604/101
5,545,133 A	8/1996	Burns et al. ....	604/96
5,695,468 A	12/1997	Lafontaine et al. ....	604/96
5,718,683 A *	2/1998	Ressemann et al. ....	604/96.01
5,785,685 A	7/1998	Kugler et al. ....	604/96
5,807,330 A	9/1998	Teitelbaum ....	604/96
5,833,644 A	11/1998	Zadno-Azizi et al. ....	604/52
5,833,650 A	11/1998	Imran ....	604/53
5,925,016 A	7/1999	Chornenky et al. ....	604/96
6,027,476 A *	2/2000	Sterman et al. ....	604/96.01
6,056,721 A *	5/2000	Shulze ....	604/102
6,319,228 B1 *	11/2001	Kastenhofer ....	604/96.01
2001/0041862 A1 *	11/2001	Glickman ....	604/101.01

**FOREIGN PATENT DOCUMENTS**

(21) Appl. No.: **09/512,994**

(22) Filed: **Feb. 24, 2000**

(51) **Int. Cl.<sup>7</sup>** ..... **A61M 29/00**

(52) **U.S. Cl.** ..... **604/96.01; 604/528**

(58) **Field of Search** ..... 604/96.01, 102, 604/101.01, 22, 528, 101.05, 97.01, 97.02, 99.01, 164.01, 164.09, 523; 600/486

(56) **References Cited**

**U.S. PATENT DOCUMENTS**

3,087,492 A	4/1963	Garth .....	128/350
3,211,150 A	10/1965	Foderick .....	128/349
3,908,267 A	9/1975	Loyd et al. ....	29/631
3,982,544 A	9/1976	Dyck .....	128/349 R
4,028,037 A	6/1977	Dawson .....	425/392
4,205,683 A	6/1980	O'Neill .....	128/348
4,205,691 A	6/1980	Patel .....	128/774
4,333,452 A	6/1982	Au .....	128/205.24
4,445,892 A *	5/1984	Hussein et al. ....	604/101.05
4,506,691 A	3/1985	Tseo .....	137/1
4,517,979 A	5/1985	Pecenka .....	128/325
4,696,304 A *	9/1987	Chin .....	600/486
4,800,109 A	1/1989	Washizu .....	428/34.9
4,902,095 A	2/1990	Baker et al. ....	350/96.21
4,923,498 A	5/1990	Gregory .....	65/109
4,968,306 A	11/1990	Huss et al. ....	604/264
5,059,176 A	10/1991	Winters .....	604/96
5,120,323 A *	6/1992	Shockey et al. ....	604/528
5,160,321 A *	11/1992	Sahota .....	604/96.01
5,167,239 A	12/1992	Cohen et al. ....	128/772
5,171,221 A	12/1992	Samson .....	604/96
5,324,255 A *	6/1994	Passafaro et al. ....	604/22
5,336,174 A	8/1994	Daoud et al. ....	604/30
5,423,742 A	6/1995	Theron .....	604/28
5,449,343 A	9/1995	Samson et al. ....	604/96

EP	0 272 112 A2	6/1988
EP	0 402 467 A1	12/1990
EP	0 547 358 A3	6/1993
EP	0 547 358 A2	6/1993
EP	0 569 030 A1	11/1993
EP	0 710 490 A3	5/1996
EP	0 710 490 A2	5/1996
GB	2 139 725 A	11/1984
WO	WO 92/13589 A1	8/1992
WO	WO 97/44082 A2	11/1997
WO	WO 97/44085 A2	11/1997
WO	WO 98/38930 A1	9/1998
WO	WO 99/26692 A1	6/1999
WO	WO 99/42161 A2	8/1999
WO	WO 99/45835 A2	9/1999

\* cited by examiner

*Primary Examiner*—Teresa Walberg

(74) *Attorney, Agent, or Firm*—Crompton, Seager & Tufte, LLC

(57) **ABSTRACT**

An occlusion device for occluding a body conduit including an elongate tubular shaft having an inflatable balloon disposed near the elongate shaft distal end and a proximal seal having a sufficiently small profile to allow a second catheter to pass over the distal occlusion device while the inflatable balloon remains uninflated. One occlusion device includes an elongate fluid displacement rod within the occlusion device elongate shaft, providing both a fluid pressure source and a seal. The elongate rod can be rapidly advanced and retracted, providing rapid and controlled inflation and deflation of the distal balloon.

**9 Claims, 5 Drawing Sheets**

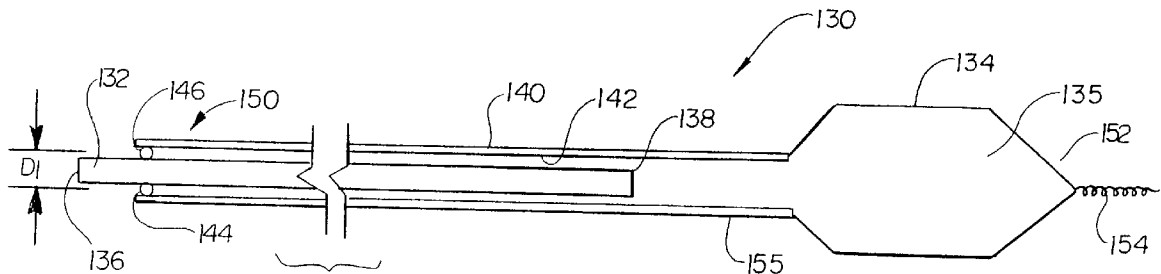


Fig. 1

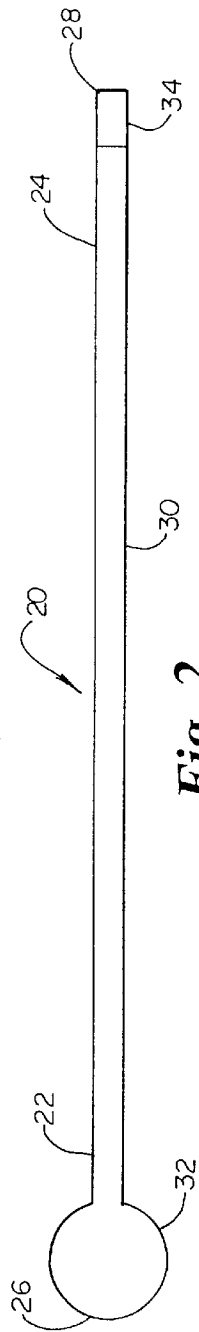


Fig. 2

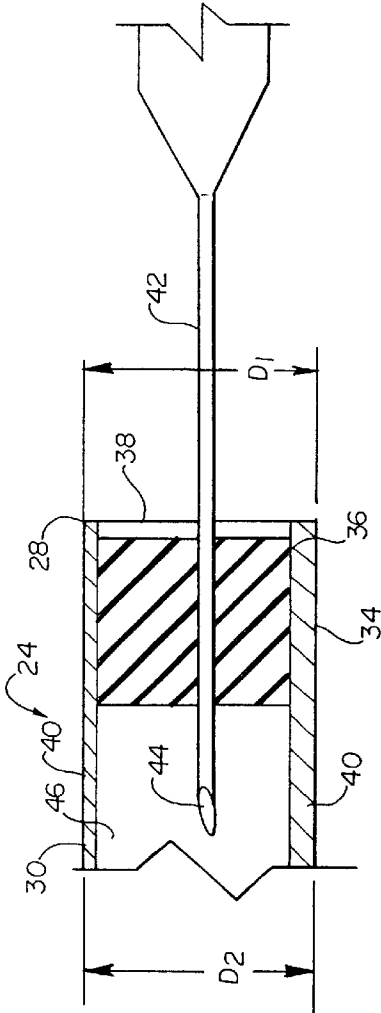


Fig. 3

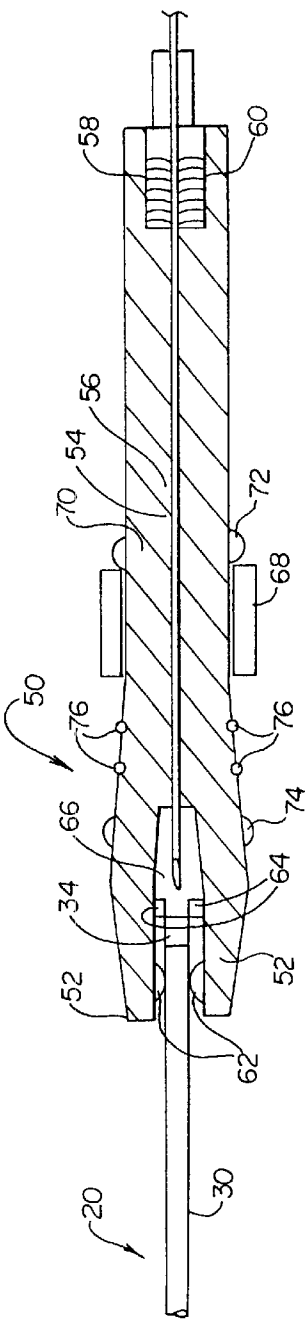


Fig. 4

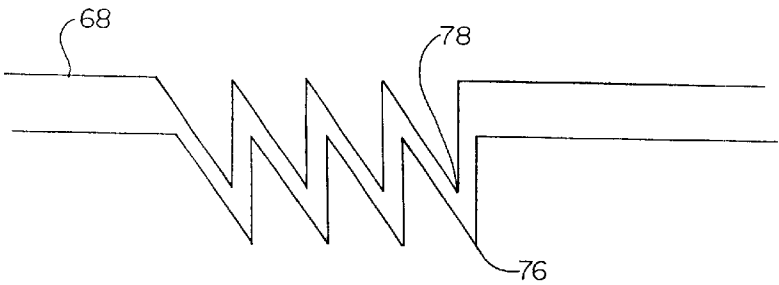
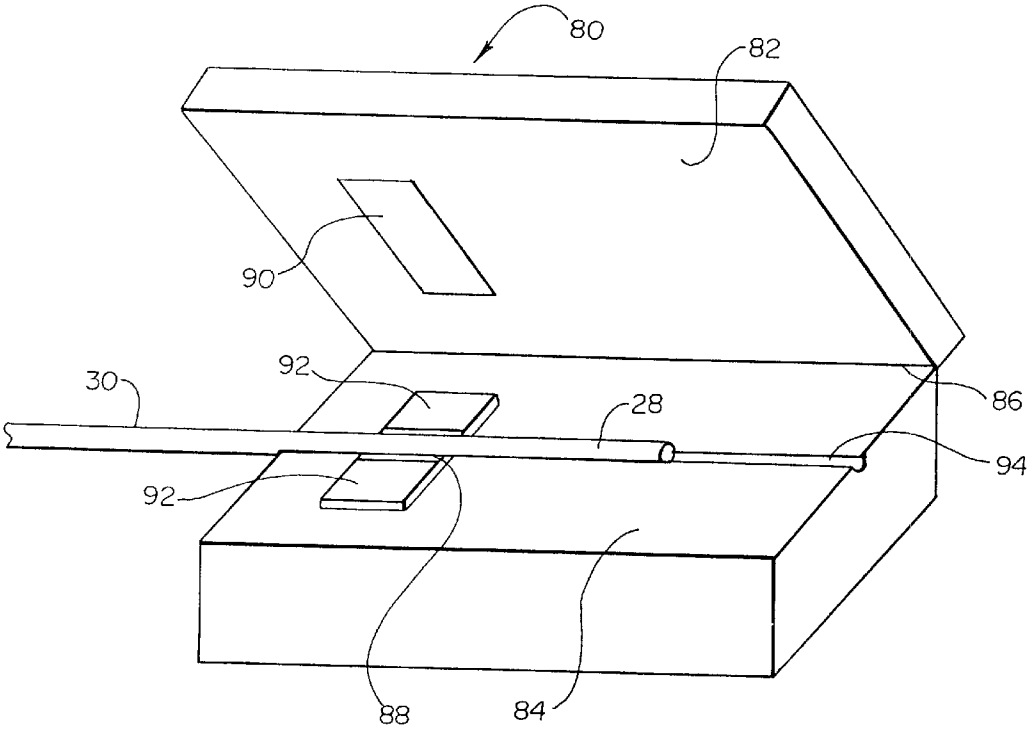
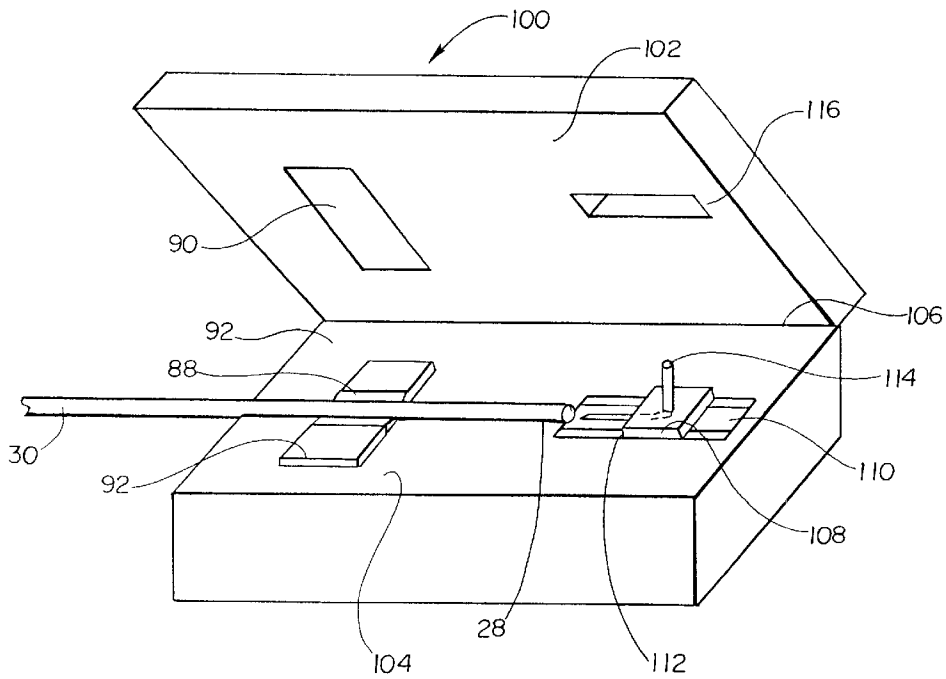


Fig. 5



**Fig. 6**



**Fig. 7**

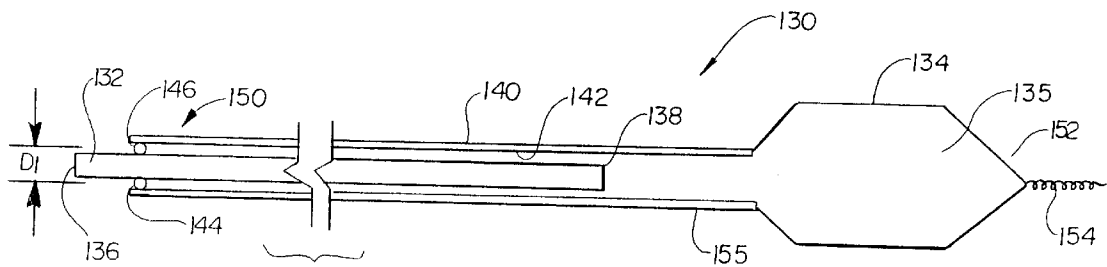


Fig. 8

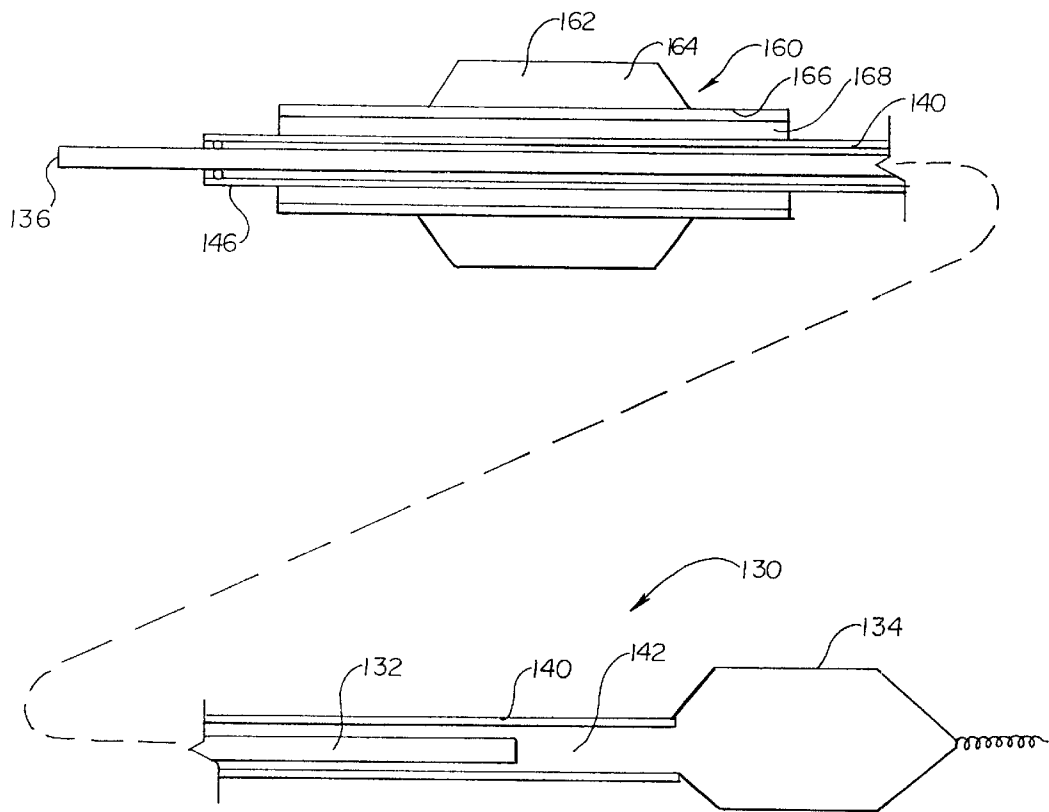
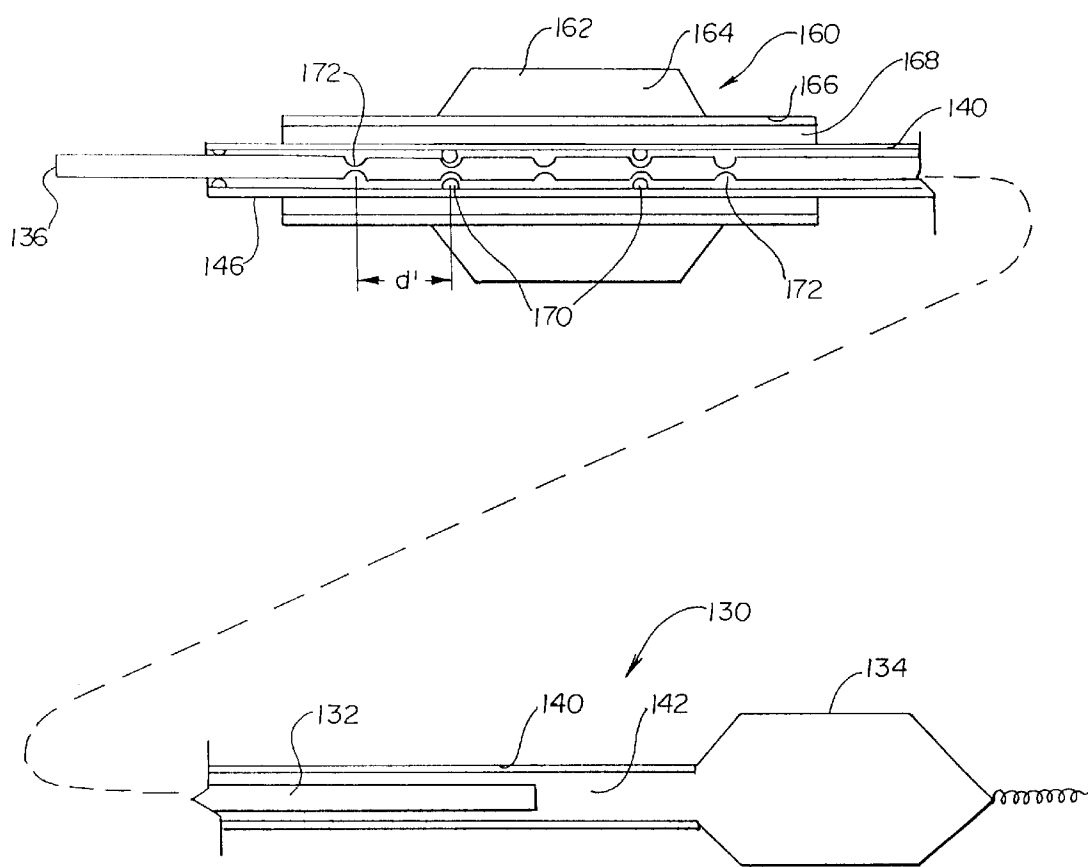


Fig. 9



**OCCUSION DEVICE****RELATED APPLICATIONS**

The present application is related to U.S. application Ser. No. 08/308,025, filed Sep. 16, 1994, entitled **BALLOON CATHETER WITH IMPROVED PRESSURE SOURCE**, now U.S. Pat. No. 5,545,133; U.S. application Ser. No. 08/586,514, filed Jan. 16, 1996, entitled **BALLOON CATHETER WITH IMPROVED PRESSURE SOURCE**, now U.S. Pat. No. 5,695,468; and U.S. application Ser. No. 08/812,390, filed Mar. 5, 1997, entitled **BALLOON CATHETER WITH IMPROVED PRESSURE SOURCE**, now U.S. Pat. No. 5,785,685, the disclosures of which are hereby incorporated by reference.

**FIELD OF THE INVENTION**

The present invention is related generally to medical devices. More specifically, the present invention is directed to occlusion catheters. Catheters of the present invention incorporate devices and methods allowing a balloon or other occlusion device to be inflated or expanded and remain inflated or expanded while a second catheter is advanced over the proximal end of the occlusion catheter.

**BACKGROUND OF THE INVENTION**

Body vessels and conduits, for example coronary arteries, the carotid artery, and lumens of the biliary tree, are frequently treated from within using catheters having means for treating conditions or affected areas at locations within the vessels. Treatment device examples include angioplasty balloons, stents and associated stent delivery catheters, drug delivery catheters, atherectomy devices, and devices for crushing or dissolving blockages in the biliary tree. When using these and other devices, it may be desirable to position and expand an occlusion device such as an inflatable distal occlusion balloon in proximity to the device. In coronary artery applications, the occlusion device can be disposed distally and downstream of the more proximal treatment apparatus such as a rotatable atherectomy burr or an angioplasty balloon. In this application, the occlusion device is a distal occlusion device. A distal occlusion device may also be placed downstream of a stent and associated stent delivery catheter while the stent is being expanded against the vessel wall.

Distal occlusion devices can be used to prevent byproducts of treatment from leaving the treatment area. For example, small particles of plaque may be freed by an atherectomy process. Distal occlusion devices may also be used to provide a quiescent region of a body vessel where treatment can occur. In one example, a coronary artery region may be blocked off from blood flow to allow treating a stenosed region vessel wall with an agent to inhibit restenosis. In another example, a stone may be isolated between a distal and a proximal occlusion balloon, with the space being filled with a chemical to dissolve the stone. In many of these applications, the vessel region proximal of the distal occlusion device is aspirated through a catheter lumen to remove byproducts prior to deflating or removing the distal occlusion device.

An alternative application of an occlusion device is disclosed by Parodi et al. in published PCT Application WO 99/45835. The Parodi et al. disclosure is directed to an occlusion device to guard against embolization during carotid angioplasty. The occlusion device is placed within the vessel lumen proximal to the treatment site, and the

device is expandable against the vascular duct to occlude the anterograde blood flow while a vacuum suction device is used to reverse blood flow distal of the occlusion device. The occlusion device includes a mouth for drainage of the retrograde blood flow containing any emboli therein. In this way, the protective device allows the temporary reversal of the flow of blood to prevent emboli from reaching the brain and allows for the drainage of emboli to the outside of the patient's body. During treatment with an angioplasty balloon distal of the occlusion device, the occlusion device in conjunction with vacuum suction and monitoring of the patient's blood flow allows controlled reversal of the blood flow.

Inflating an occlusion device is often accomplished in a manner similar to inflating an angioplasty balloon. Proximal manifolds and adapters such as Luer fittings can provide a secure channel between a pressurized fluid supply outside the body and the distal occlusion device such as a balloon. Luer fittings are often bulky and significantly larger than the tubes to which they are attached. Because it may be required to advance a second catheter over the occlusion catheter while the occlusion catheter remains in place, it is generally not possible to advance a second catheter over the occlusion catheter while the conventional fitting is attached. If the conventional fitting were removed from the occlusion device catheter shaft, the distal occlusion device shaft proximal end would require sealing to avoid loss of inflation pressure. The seal itself would have to be small enough to allow the second catheter to pass over the seal while the seal maintained the pressure within the occlusion device and balloon.

Examples of a low profile occlusion device are described by Zadno-Azizi et al. in published PCT application No. WO 99/26692 and by Teitelbaum in U.S. Pat. No. 5,807,330. Both the Zadno-Azizi et al. and Teitelbaum devices never become completely sealed systems during operation. Both devices have proximal ports that must be opened and closed when inflating or deflating the occlusion balloon.

What would be advantageous is an occlusion catheter having a proximal end profile sufficiently small so as to allow a second catheter to be advanced over the proximal end of the occlusion balloon catheter shaft, while maintaining the occlusion balloon in an inflated state. A device allowing inflation and rapid deflation while a catheter is inserted over the distal occlusion catheter would be desirable as well. A device that does not require opening and closing a part to operate the balloon would also be desirable.

**SUMMARY OF THE INVENTION**

The present invention provides occlusion devices for occluding body conduits and vessels. The devices include expandable distal portions and an elongate tubular shaft. The occlusion devices allow other devices to be advanced over and retracted from the occlusion device shafts while the occlusion devices occlude the conduit or vessel. One device includes an elongate tubular shaft having an inflatable occlusion device disposed near the distal end and a lumen extending within the shaft walls. An elongate fluid displacement rod is disposed within the shaft. The fluid displacement rod is preferably at least half the length of the tubular shaft length. The tubular shaft can have a distal fluid preparation portion near the distal balloon for infusing inflation fluid into the shaft prior to use.

In use, the elongate fluid displacement rod can be advanced distally, wherein the volume of the rod within the lumen forces an equal volume of fluid into the distally disposed balloon. The fluid displacement rod can provide

precise linear control of the amount of fluid forced into the balloon and a linear relationship between the linear displacement of the rod and the fluid in the balloon. The placement of the rod also provides control of pressure within the balloon. The rod can also provide for rapid inflation of the balloon and rapid deflation of the balloon. Rapid deflation can be advantageous where it is desirable for the occlusion to be ended or reduced rapidly in order to restore fluid flow. One example of this advantage may be found in rapidly deflating a distal occlusion balloon where the balloon is occluding a coronary vessel and patient condition indicates that rapid balloon deflation may be called for.

Another aspect of the invention includes alignment devices for aligning hypodermic needles for insertion into the proximal end of occlusion devices. The hypodermic needle alignment devices are particularly suitable for use with distal occlusion devices having proximally disposed sealable or self-sealing seals.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic plan view of a representative occlusion device having a proximal seal, suitable for use with one aspect of the present invention;

FIG. 2 is a longitudinal cross-sectional view of the proximal region of the occlusion device of FIG. 1, illustrating injection of inflation fluid through a self-sealing valve;

FIG. 3 is a longitudinal cross-sectional view of a jawed alignment device for aligning the needle for penetration through the device seal of FIG. 2;

FIG. 4 is an enlarged schematic view of detents on the alignment device of FIG. 3;

FIG. 5 is a perspective view of an alignment device for aligning a side entry hypodermic needle with the shaft of an occlusion device such as the device of FIG. 1;

FIG. 6 is a perspective view of an alignment device for aligning a top entry, curved hypodermic needle, with the shaft of an occlusion device such as the device of FIG. 1;

FIG. 7 is a fragmentary, longitudinal cross-sectional view of an occlusion device having a fluid displacement rod disposed within the inflation lumen;

FIG. 8 is a fragmentary, longitudinal cross-sectional view of the occlusion device of FIG. 7, having a second catheter disposed over the occlusion device shaft; and

FIG. 9 is a fragmentary, longitudinal cross-sectional view of the device of FIG. 8, incorporating features to incrementally inflate the occlusion balloon.

#### DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates an occlusion device 20 having a distal region 22, a proximal region 24, a distal end 26, a proximal end 28, an elongate tubular shaft 30, a distally disposed occlusion balloon 32, and a proximally disposed seal 34. Occlusion device 20 illustrates one type of occlusion device suitable for use with a hypodermic needle alignment device, described later. Balloon 32 can be formed of a non-compliant polymeric material such as polypropylene, polyethylene and nylon or compliant polymeric materials such as polyvinyl chloride, olefin copolymers and ionomer resins, in a manner well known to those skilled in the art. The elongate tubular shaft 30 is preferably made of a material such as stainless steel hypotubing or other materials well known to those skilled in the art such as a relatively stiff polymer or a nickel titanium alloy.

FIG. 2 illustrates part of the elongate shaft proximal portion 24 of FIG. 1 in greater detail. Seal 34 can be formed

of a sealable or self-sealing material such as medical grade silicone rubber or other suitable polymeric material, which is illustrated as forming a proximal plug region 36. Seal 34 can also include a proximalmost layer 38 formed of a material such as polycarbonate. Proximal seal or plug portion 36 can be formed by injecting a polymeric material between walls 40 of elongate shaft 30 to fill the lumen therein. Proximalmost film or barrier 38 can be a formed by affixing polymeric material over proximal end 28. A hypodermic needle 42 having a sharp end 44 can be inserted through seal material 36 and into a lumen 46 disposed between walls 40. In use, hypodermic needle 42 or other suitable injection device may be used to inject inflation fluid into lumen 46 to inflate balloon 32. Proximal end 38 has an outside diameter as indicated at D1. At a more distal portion within proximal region 24, elongate shaft 30 has an outside diameter D2. In one embodiment, D1 and D2 are substantially equal, elongate shaft 30 having a substantially uniform outer diameter over much of its length. In one embodiment, D1 is equal to D2. In another embodiment, D1 is only slightly larger than D2. In a preferred embodiment, D1 is not substantially larger than D2. Having the outside diameter of elongate shaft proximal end 28 substantially equal to the outside diameter of the shaft provides a small profile for advancing other devices over elongate shaft 30. In particular, in a preferred embodiment, there is no proximal seal having an outer diameter substantially larger than the outer diameter of the shaft, for example at the shaft midpoint well distal of the proximal region seal.

Having a distal occlusion device with a proximal end outside diameter approximately the same as the shaft outside diameter at its midpoint longitudinally can provide an elongate shaft which can be used for advancing a second medical device over the elongate shaft. Elongate shaft 30 can thus be used in ways similar to a guide wire. In one use, elongate shaft 30 can be used to guide a therapeutic device such as an atherectomy catheter, an angioplasty catheter, or a stent delivery catheter over the shaft. In another use, elongate shaft 30 can be used to guide a diagnostic device such as an angiography catheter over its length. "Over the wire" catheters can be guided to a target site, having shaft 30 disposed within most of their length. Single operator exchange catheters can be guided to a target site, having elongate shaft 30 disposed primarily within a distal region of the device. For such uses, it is preferred that the shaft have an outside diameter of about 0.010 inches to about 0.018 inches.

It may be possible for hypodermic needle 40 to be hand guided into proximal seal 34. Given the small dimensions of the distal occlusion device catheter shaft, however, guiding a hypodermic needle into the proximal seal can be difficult. Referring now to FIG. 3, an alignment device 50 is illustrated. Alignment device 50 can be used to guide a hypodermic needle into the proximal end of a distal occlusion device. In one embodiment, alignment device 50 includes two opposing jaws 52 disposed about elongate shaft 30. Another embodiment has three jaws, preferably spaced equidistantly about shaft 30. In other embodiments, multiple jaws, fingers, or a single cylindrical mouth may be disposed about elongate shaft 30. The alignment device illustrated includes a hypodermic needle 54 disposed within a lumen 56 extending through the central longitudinal axis of the device 50. Needle 54 has a lumen which is in fluid communication with a proximal fitting 58 which can be used for attachment to an inflation fluid source such as a syringe. In one embodiment, proximal fitting 58 includes a series of internal threads 60 for attachment of a syringe. In the distal end near the jaws, one embodiment includes a pair of alignment pads

5

62 for grasping shaft 30. Alignment pads 62 can be formed of elastomeric gripping material for grasping shaft 30. One embodiment also includes a pair of stops 64 for positioning the occlusion device proximal end. In the embodiment illustrated, a sharp distal end 66 of needle 56 is shown protruding toward seal 34.

In one embodiment, a clamp is included for forcing together jaws 52 about catheter shaft 30. The clamping device can be used to securely fix alignment device 50 to distal occlusion device 20 prior to inserting the needle. In one embodiment, the clamping device includes a collar or sleeve 68 disposed about alignment device 50 at a mid portion 70. Collar 68 can be disposed between a proximal stop 72 and a distal stop 74. In one embodiment, proximal stop 72 and distal stop 74 are formed as annular rings about the device. In another embodiment, discrete protruding regions or bumps form the proximal and distal stops. The alignment device can also include detents 76 securely engaging corresponding structures on the clamping collar 68. FIG. 4 illustrates in greater detail one embodiment of detents 76 and corresponding teeth 78 on the clamping collar 68. Collar 68 can also be threadably secured between stops 72 and 74. This eliminates the need for detents. As the collar is advanced across the mid portion, a wider jaw section, the jaws are forced inward to clamp on catheter shaft 30.

In use, jaws 52 can be disposed about seal 34 which is guided between alignment pads 62. With shaft 30 somewhat aligned, clamping ring 68 can be slid proximally toward jaws 52. Shaft 30 can be slid further into jaws 50 across alignment pads 62 until stops 64 is reached. In one embodiment, the distal end of needle 56 extends distally past stops 64 such that when seal 34 is finally in contact with stops 64, the distal end of needle 56 extends sufficiently far into catheter shaft 30 so as to be in fluid communication with distal occlusion device lumen 46. At this point, rings 68 can be slid distally to engage detents 76, and in some embodiments, to abut distal stops 74. With alignment device 50 securely affixed to shaft 38, fluid can be injected through needle 56, into shaft 30, into an occlusion balloon.

Referring now to FIG. 5, another alignment device 80 is illustrated. Alignment device 80 includes a first or top surface 82 and an opposing second or bottom surface 84. Alignment device 80 includes a longitudinal channel 88 disposed on second surface 84 and a grasping pad 90 is disposed on first surface 82. Other embodiments have channels or partial channels in both the first and second surfaces and can include other means for grasping. Catheter shaft 30 is illustrated disposed longitudinally and within longitudinal channel 88. In the device illustrated, a pair of pads 92 are disposed on either side of longitudinal channel 88, with both pads 92 and 90 being formed of an elastomeric material. In one embodiment, longitudinal channel 88 allows longitudinal, but not lateral, movement of shaft 30. In another embodiment, the geometry of longitudinal channel 88 and pads 92 are such that both longitudinal and lateral movement of shaft 30 is precluded after first and second surfaces 82 and 84 are fully brought together. A second longitudinal channel 94 is illustrated, also along the longitudinal axis of shaft 30. Again, channel 94 can be formed as either a full or partial channel in both the first and second surfaces 82 and 84. In one embodiment, channel 88 and corresponding pads 92 preclude lateral and longitudinal movement of shaft 30 once enclosed, and second channel 94 allows longitudinal, but not lateral, movement of an inserted hypodermic needle.

In use, a device such as alignment device 80 can, in the open position, receive an inserted catheter shaft such as shaft

6

30 within longitudinal channel 80. With proximal end 28 in position, first surface 82 and second surface 84 can be closed about hinge 86, laterally and longitudinally immobilizing shaft 30. A hypodermic needle can be inserted into longitudinal channel 94, bringing the sharp tip of the hypodermic needle into shaft proximal end 28. With shaft 30 firmly held in place, inflation fluid can be injected from the hypodermic needle into shaft 30.

Referring now to FIG. 6, another alignment device 100 is illustrated, being similar in many respects to alignment device 80 illustrated in FIG. 5. Alignment device 100 includes a first surface 102 and a second opposing surface 104, attached to each other about a hinge 106. Pads 90 and 92 can be as illustrated in FIG. 5, and as previously discussed. In the embodiment illustrated, device 100 includes longitudinal channel 88 and has a carrier 108 disposed within a second longitudinal channel 110 shown on second surface 104. Carrier 108 is preferably slidably mounted within second channel 110, providing for longitudinal movement toward and away from shaft proximal end 28. A curved or bent hypodermic needle 112 is mounted on carrier 108 and can be received within shaft proximal end 28. Hypodermic needle 112 is illustrated having a proximal port 114 which can protrude through a substantially longitudinal slot 116 in first surface 102.

In use, shaft 30 can be disposed between pads 90 and 92 within longitudinal channel 88. First surface 102 can be brought into close proximity to second surface 104, allowing hypodermic needle proximal port 114 to protrude through longitudinal slot 116. With the first and second surfaces brought together, hypodermic needle proximal port 114 can protrude through the top of device 100. A syringe or other fluid source can be attached to hypodermic needle port 114, preferably after the first and second surfaces are brought together. Before attachment of the fluid source such as a syringe, carrier 108 can be longitudinally slid toward shaft proximal end 28, causing hypodermic needle 112 to protrude sufficiently far into shaft 30. Inflation fluid can then be injected through hypodermic needle 112 and into shaft 30, inflating a distal occlusion device. Alignment device 100 has the advantage of allowing the syringe and hypodermic to be inserted into the proximal port 114 after the first and second opposing surfaces are closed. After inflation, the fluid source can be detached from port 114, and the opposing surfaces opened. Slidable hypodermic needle 112 can be retracted out of shaft seal region 28.

Referring now to FIG. 7, an inflatable occlusion device 130 is illustrated, extending from a proximal region 150 to a distal region 152. Occlusion device 130 can terminate distally as illustrated, in an atraumatic tip such as a spring coil tip 154. Occlusion device 130 includes a pushable elongate rod or displacement rod 132 inserted through the device, which can be used to displace inflation fluid from the proximal portion of the shaft lumen into an occlusion balloon 134. Occlusion device 130 functions similar to the inflatable device described in U.S. Pat. No. 5,785,685 entitled BALLOON CATHETER WITH IMPROVED PRESSURE SOURCE, the disclosure of which is herein incorporated by reference in that the displacement rod movement inflates and deflates the balloon. Displacement rod 132 has an outer diameter D1 indicated near a proximal end 136 of rod 132. Rod 132 includes a distalmost end 138 illustrated as disposed distally well into device 130.

Displacement rod 132 is illustrated as directly disposed within an elongate tubular member 140 having a shaft distal region 155 proximal of balloon 134 and a lumen 142 within. Lumen 142 can serve as a means for inflating device 130,

7

containing inflation fluid which can be displaced by rod **132** which forces fluid into distally disposed occlusion balloon **134**. Inflation fluid can be retained within lumen **142** by a proximal seal **144** disposed between rod **132** and tube **140**. In preferred embodiments, the displacement rod **132** is preferably pre-loaded into lumen **142** during manufacturing, with fluid filling the shaft lumen. Alternatively, the catheter could be prepped on-site. In either application, proper function of the displacement rod requires venting substantially all compressible gas from the lumen and balloon interior. One such method and device is disclosed in U.S. Pat. No. 5,785,685, wherein a one-way valve is provided to force gas from the distal portion of the catheter out the proximal end by injection of fluid through the one-way valve.

In use, occlusion device **130** can also be prepared by injecting inflation fluid into lumen **142** sufficient to largely fill the length of the lumen. After the initial filling with inflation fluid, displacement rod distal end **132** can be displaced near a proximal end **146** of outer tube **140**. After device **130** is inserted well into the body, displacement rod **132** can be advanced distally, thereby forcing inflation fluid from lumen **142** into balloon **134**, thereby inflating balloon **134**. As can be seen in FIG. 7, displacement rod **132** provides a small proximal profile for device **130**, which can allow a second catheter to be inserted over outer tube proximal end **146**, thereby using outer tube **140** as a guide wire to guide a second catheter into position.

Other methods and devices can also be used to prepare the occlusion device **130** for use. Inflation fluid can be injected into tube **140** after pulling a vacuum on tube **140** and balloon **134**, using methods well known to those skilled in the art. Inflation fluid can also be initially injected into outer tube **140** using features and procedures described in U.S. patent application Ser. No. 09/208,145, filed Dec. 9, 1998, entitled CATHETER WITH DISTAL MANIFOLD PREP VALVE/MANIFOLD, the disclosure of which is herein incorporated by reference. As described in the aforementioned application, inflation fluid can be injected into tube **140** through an additional valve disposed near catheter shaft distal region **144**. Injecting inflation fluid from a distal location has the advantage of forcing any air proximally out of the shaft.

Distal occlusion device **130** can be both rapidly inflated and deflated, relative to a syringe inflated catheter of similar dimensions. Using a fluid displacement rod as the inflation fluid pressure source can also provide control over balloon inflation through control over linear position of the fluid displacement rod. In particular, the ability to rapidly deflate the balloon can be advantageous in coronary artery applications, where patient indications may require rapid deflation of the balloon.

Referring now to FIG. 8, distal occlusion device **130** is further illustrated having a second catheter **160** disposed over outer tube **140**. Second catheter **160** can be a therapeutic or diagnostic catheter. In the example illustrated, second catheter **160** is a highly diagrammatically illustrated angioplasty balloon catheter, having only the distal region illustrated. Second catheter **160** includes a distal balloon **162** having interior **164** which is disposed about an elongate tube **166** having a lumen **168** for receiving a guide wire and/or outer tube **140** of the first or occlusion catheter **130**. FIG. 8 illustrates how a second catheter can be inserted over the distal occlusion catheter where the distal occlusion catheter proximal profile is sufficiently small so as to fit within the lumen of the second catheter. In some embodiments, not requiring illustration, after displacement rod **132** is moved distally further into occlusion device lumen **142**, the dis-

8

placement rod proximal end can be clamped in a desired position to maintain inflation of distal occlusion balloon **134** while enclosed by outer tube **146**.

Referring now also to FIG. 9, an alternative embodiment of the catheter of FIG. 8 is depicted. The embodiment of FIG. 9 includes the additional feature of radial expansion of balloon **134** being incrementally controlled through a ratcheting or detent mechanism **170** that interacts with corresponding indentations **172** on displacement rod **132**. As shown in FIG. 9, the detents include projections extending radially inward. One or more of such detents can be incorporated in combination with one or more indentations on the displacement rod. The combination of detents and indentations can also act to enhance the desired seal **144**, necessary for use. Thus, in alternative embodiments, the combination of detents and indentations could replace the seal or work in combination with the seal. The distance  $d'$  between detents **170** are preferably set to correspond to certain degrees of radial expansion of balloon **134**. For example, each distance  $d'$  rod **132** is moved in a proximal to distal direction could correspond to a 0.5 mm increase in diameter of balloon **134**. Correspondingly, each distance  $d'$  displacement rod **132** is moved in the distal to proximal direction would result in a 0.5 mm decrease. Other mechanisms for controlling incremental changes in radial expansion of balloon **134** include markings on the side of displacement rod **132**. A threaded design is also possible.

In use, distal occlusion catheter **130** preparation can include first filling the catheter with inflation fluid while maintaining balloon **134** in an uninflated state. Fluid displacement rod **132** can be inserted into a proximal portion of outer tube **140**. The distal occlusion device with rod partially inserted can be advanced past a target site in a body conduit such as a coronary artery. Second catheter **160** can be advanced over first catheter outer tube **140**, receiving outer tube **140** within lumen **168**. Second catheter **160** can be advanced to a treatment site, and distal occlusion device **130** can be inflated by advancing rod **132** distally within tube **140**. With the vessel occluded, catheter **160** can be used to treat the target site. In some applications, for example, this may include either angioplasty or atherectomy.

Numerous advantages of the invention covered by this document have been set forth in the foregoing description. It will be understood, however, that this disclosure is, in many respects, only illustrative. Changes may be made in details, particularly in matters of shape, size, and arrangement of parts without exceeding the scope of the invention. The invention's scope is, of course, defined in the language in which the appended claims are expressed.

What is claimed is:

1. A device for treating a body vessel region while occluding a more distal body vessel region comprising:

a first catheter including a first elongate tubular shaft having a proximal region, a distal region, a proximal end, and a first lumen therethrough, an inflatable balloon disposed near said first shaft distal region and having an interior in fluid communication with said first lumen, and a fluid displacement rod having a portion thereof slideably disposed in said tubular member such that said balloon may be expanded upon longitudinal actuation of said rod; and

a second catheter including a second elongate tubular shaft having a second lumen therethrough, wherein said second catheter second lumen is dimensioned to slide over said first catheter shaft while said first catheter balloon remains inflated with inflation fluid.

9

2. A device for treating a body vessel region as recited in claim 1, further comprising a seal connected to said tubular member proximal end and disposed about said displacement rod to create a liquid seal between the inside of said tubular member and said displacement rod.

3. A device for treating a body vessel region as recited in claim 1, wherein said first catheter has a length and said elongate fluid displacement rod has a length at least half said catheter length disposed within said first catheter lumen.

4. A device for treating a body vessel region as recited in claim 1, wherein said second catheter includes a second inflatable balloon disposed near said second catheter shaft distal region.

5. A method for treating a body vessel target region comprising the steps of:

providing a first catheter including a first elongate tubular shaft having a proximal region, a distal region, and a first lumen therethrough, an inflatable balloon disposed near said first shaft distal region and having an interior in fluid communication with said first lumen, and a fluid displacement rod having a portion thereof slidably disposed in said tubular shaft such that said balloon may be expanded upon longitudinal actuation of said rod;

providing a second catheter having a second elongate tubular shaft having a distal region and a second lumen therethrough and having means for treating said vessel region disposed near said second shaft distal region;

10

advancing said first catheter to a position distally past said target region;

inflating said first catheter balloon by inserting said fluid displacement rod into said first catheter lumen and forcing fluid into said first catheter balloon;

maintaining said first catheter balloon inflation by maintaining fluid pressure in said first catheter shaft lumen;

advancing said second catheter over said first catheter shaft by inserting said first catheter shaft proximal end into said second catheter shaft lumen distal end; and

treating said vessel site with said second catheter treating means.

6. A method as recited in claim 5, wherein said treating means is selected from the group consisting of angioplasty balloons and atherectomy devices.

7. A method as recited in claim 5, wherein said inflating step is performed before said second catheter advancing step.

8. A method as recited in claim 5, wherein said inflating step is performed after said second catheter advancing step.

9. A method as recited in claim 8, further comprising a deflating step including deflating said balloon caused by retracting said fluid displacement rod.

\* \* \* \* \*